Comment's to:
Implementation of the Advanced Therapies' Regulation
Regulation (EC) No 1394/2007
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Section	Cook Medical Comments
2.2 Overarching GCP principles section 2 p. 4: *Subjects should be followed- up during and after the completion of the clinical trial both for their own care and to allow data collection as needed.*	Currently subjects are usually not followed up after completion of the clinical trial. The follow-up phase is included in the clinical investigation plan and is as such a part of the clinical trial. If subjects are to be followed after the follow-up phase described in the clinical investigation plan (after completion of the clinical trial), it would be useful with some guidelines/specifications on the follow up period expected and what kind of follow up is expected.
2.3 Traceability p. 5 2.3.1 General Requirements *Where the tissues or cells are of animal origin the requirements for traceability are also applicable and should ensure there is a clear documented link from the donor to the animal to the human clinical trial subject and vice versa.*	It has been discussed whether it is feasible to make full traceability of tissues or cells of animal origin back to every single animal.
2.4. Safety reporting and long term follow-up p. 8 2.4.1 Notification of Adverse Events *New events related to the conduct of the trial or the development of the ATIMP and likely to affect the safety of the subjects should be reported. This includes:* - *a serious adverse event which could be associated with the trial procedures and which could modify the conduct of the trial;* - *a significant hazard to the subject population such as lack of efficacy of an investigational medicinal product used for the treatment of a life-threatening disease*	Reporting timelines and processes for the reportable events are not mentioned in the document
2.7 GCP and Sponsor p. 11 - *The sponsor should notify serious breaches of GCP to competent authorities*	A definition of "serious breaches" should be provided. Is it major protocol non-compliances? We would propose to add 'that impacts the rights, welfare or safety of the subject or the scientific integrity of the investigation'.